Alabama Medicaid
Preferred Drug and Prior Authorization Program

Effective October 1, 2003, as a result of legislation passed in June 2003, the Alabama Medicaid Agency implemented a mandatory Preferred Drug List (PDL). Brand preferred drugs, generics and over-the-counter (OTC) drugs for classes reviewed that are covered by Medicaid are available without prior approval. If, however, a non-preferred drug is ordered, the practitioner will need to get prior authorization (PA). If approval is given to dispense the non-preferred drug, an authorization number will be given. Antipsychotic and HIV/AIDS drugs are exempt from the PDL.

The following entries contain detailed instructions on completing the Medicaid Prior Authorization Form.

Section 1: General Information
Section 2: Patient Information
Section 3: Prescriber Information
Section 4: Dispensing Pharmacy Information
Section 5: Drug/Clinical Information
Section 6: Drug Specific Information
Section 7: Exempt Medications

Section One: General Information

- **Preferred Drugs**

The following classes of drugs are on the mandatory preferred drug list:

- **Alzheimer's Agents**
- **Antidepressant Agents**
- **Antidiabetic Agents**
- **Antihypertensive Agents**
- **Anti-infective Agents**
- **Antilipemic Agents**
- **Anxiolytic, Sedative, Hypnotic Agents**
- **Cardiac Agents**
- **Cerebral Stimulants/Agents used for ADD/ADHD**
- **EENT Antiallergic Agents**
- **EENT Vasoconstrictor Agents**
- **Estrogen Agents**
- **Intranasal Corticosteroid Agents**
- **Narcotic Analgesic Agents**
- **Platelet-Aggregation Inhibitor Agents**
- **Proton Pump Inhibitors (PPI)**
- **Respiratory Agents**
- **Skeletal Muscle Relaxant Agents**
- **Skin and Mucous Membrane Agents**

- **Triptan Agents**

  Other drug classes will be added as they are reviewed and approved.

- **Stable Therapy**

  Stable therapy applies in some classes for patients who have been stable on the same drug and the same strength. Stable therapy applies for all classes listed below for children 18 years old and under. The application of stable therapy for adults is limited to the specific classes listed under the heading "Stable therapy for all ages". The term consecutive therapy addresses "stable" and is to allow approval for patients who have been determined to be stable on the medication for a specified timeframe and who continue to require therapy. Documentation of the source of medication must be provided in order to meet stable therapy requirements. Examples of acceptable documentation include pharmacy profile printouts, prescription copies, copies of the medical record medication list or progress notes documenting strength and quantity consistent with consecutive therapy timeframes. Stable therapy does not include the use of medication samples or manufacturer vouchers. The applicable timeframes required for approval can be found below.

  Stable therapy for all ages:

  - **Alzheimer's Agents-** Approval may be given with consecutive 90-day treatment.
  - **Antidepressant Agents-** Approval may be given with consecutive 60-day treatment.
  - **Antidiabetic Agents-** Approval may be given with consecutive 60-day treatment.
  - **Antihypertensive Agents-** Approval may be given with consecutive 60-day treatment.
  - **Anti-infective Agents-** Approval may be given following institutionalization or with consecutive 60-day treatment.
  - **Cardiac Agents-** Approval may be given with consecutive 60-day treatment.
  - **Cerebral Stimulants/Agents used for ADD/ADHD-** Approval may be given with consecutive 60-day treatment.
  - **Skeletal Muscle Relaxant Agents-** Approval may be given with consecutive 60-day treatment for a chronic condition associated with spasticity.

  Stable therapy for children 18 years old and under:

  - **2nd Generation Antihistamine Agents-** Approval may be given with consecutive 60-day treatment.
  - **Antilipemic Agents-** Approval may be given with consecutive 60-day treatment.
  - **Anxiolytic, Sedative, and Hypnotic Agents-** Approval may be given with consecutive 60-day treatment.
  - **EENT Antiallergic Agents-**Approval may be given with consecutive 60-day treatment.
  - **EENT Vasoconstrictor Agents-**Approval may be given with consecutive 60-day treatment.

- **Estrogen Agents**- Approval may be given with consecutive 60-day treatment.
- **Intranasal Corticosteroid Agents**- Approval may be given with consecutive 60-day treatment.
- **Narcotic Analgesic Agents**- Approval may be given with consecutive 60-day treatment.
- **NSAID Agents**- Approval may be given with consecutive 60-day treatment.
- **Platelet-Aggregation Inhibitors**- Approval may be given with consecutive 60-day treatment.
- **Prevacid NapraPac™ -** Approval may be given with consecutive 60-day treatment.
- **Proton Pump Inhibitor (PPI) Agents**- Approval may be given with consecutive 60-day treatment.
- **Respiratory Agents**- Approval may be given with consecutive 60-day treatment.
- **Sustained-release Opioid Agonist (SROA) Agents**- Approval may be given with consecutive 60-day treatment.
- **Skin and Mucous Membrane Agents**- Approval may be given with consecutive 60-day treatment.
- **Triptan Agents**- Approval may be given with consecutive 60-day treatment.

- **Verbal Requests**

PA requests for the drugs that meet the previous drug usage requirements for approval will be accepted verbally. Verbal PA requests may be initiated by pharmacists, physicians or their authorized representative. Any drug requiring additional information or medical justification must be submitted on the required PA form. Drugs that may be requested verbally are listed below:

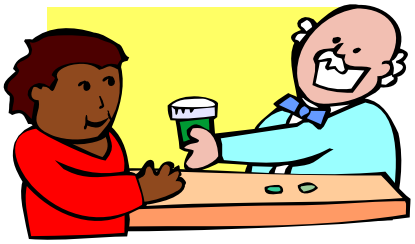
- **Alzheimer's Agents**
- **Antidepressant Agents**
- **Antidiabetic Agents**
- **Antihistamine Agents**
- **Anti-infective Agents**
- **Antilipemic Agents**
- **Anxiolytic, Sedative, Hypnotic Agents**
- **Cardiac Agents**
- **Cerebral Stimulants/Agents used for ADD/ADHD**
- **EENT Antiallergic Agents**
- **EENT Vasoconstrictor Agents**
- **Estrogen Agents**
- **H2 Antagonist Agents**
- **Intranasal Corticosteroid Agents**
- **Narcotic Analgesic Agents**
- **NSAID Agents**
- **Platelet-Aggregation Inhibitor Agents**
- **PPI Agents**
- **Respiratory Agents**
- **Skeletal Muscle Relaxant Agents**
- **Skin and Mucous Membrane Agents**
- **Triptan Agents**

- **Paper Requests**

Page one of the Prior Authorization Request Form may be submitted alone unless the medication requested is listed on page two. Check the appropriate box at the top of the form to indicate whether one or both pages are being submitted. Acknowledgement of

transmission of the second page will assure that the reviewer has all completed material needed to review the request. **A separate form will need to be completed for each drug/nutritional requested.**

- **Electronic Requests**



  - **From the Pharmacy –** Certain classes are included in the Electronic Prior Authorization (EPA) program. Once the pharmacy sends an electronic claim for a drug in the EPA program, the system reviews medical and pharmacy claims history on the patient. If the criteria is met, the claim is automatically assigned an authorization number and is then approved. If the criteria is not met, a message is sent back to the pharmacy to submit a manual request.

    Note: An EPA rejected claim does not constitute a PA denial, only a notice to the pharmacy that a manual request is needed.

    Drug classes included in the EPA program

    - Alzheimer's Agents
    - Antidepressants
    - Antihypertensives
    - Antilipemics
    - Anxiolytics/Sedatives/ Hypnotics
    - Cardiac Agents
    - Cerebral Stimulants/ADD/ADHD
    - Diabetic Agents
    - Estrogens
    - Intranasal Corticosteroids
    - NSAIDs
    - Respiratory Agents
    - Second Generation Antihistamines
    - Skeletal Muscle Relaxants
    - SROAs
    - Triptans

  - **Online Submission -** From the Medicaid website, a link can be found for a PA request form that can be completed and submitted electronically online. Online requests, once submitted, are treated like paper requests and are subject to paper request requirements.

- **PA Approval Timeframes**

Alzheimer's Agents- Approval may be given for up to 12 months.
Antidepressants- Approval may be given for up to 12 months.
Antidiabetic Agents- Approval may be given for up to 12 months.
Antihistamine- Approval may be given for up to 12 months.
Antihypertensives- Approval may be given for up to 12 months.
Anti-infectives- Approval may be given for up to 12 months.
Antilipemic Agents- Approval may be given for up to 6 months for initial request and up to 12 months for renewal requests.
Anxiolytics, Sedatives and Hypnotics- Approval may be given for up to 3 months initially and up to 6 months for renewal requests**.**

Biological Injectables- Approval may be given for up to 12 months.
Cardiac Agents- Approval may be given for up to 12 months.
Cerebral Stimulants/Agents used for ADD/ADHD- Approval may be given for up to 12 months.
EENT Antiallergic Agents- Approval may be given for up to 12 months.
EENT Vasoconstrictor Agents- Approval may be given for up to 12 months.
Estrogens- Approval may be given for up to 12 months.
Growth Hormone- Approval may be given for up to 6 months.
H2 Antagonist- Approval may be given for up to 12 months for maintenance.
Intranasal Corticosteroids- Approval may be given for up to 12 months.
Narcotic Analgesics- Approval may be given for up to 3 months with initial and renewal requests unless one of the qualifying diagnoses is indicated, then approval may be given for up to 6 months.

NSAIDs- Approval may be given for up to 12 months.
Phosphodiesterase Inhibitors- Approval may be given for up to 30 days for initial request, with up to 3 months allowed for renewal requests.
Platelet-Aggregation Inhibitors- Approval may be given for up to 12 months from the date of the most recent event.
Prevacid NapraPac™ - Approval may be given for up to 6 months for initial request and up to 12 months for renewal requests.
Prevpac®- Approval authorizes a 14 day course of therapy.
Proton Pump Inhibitor Agents- Approval may be given for up to 12 months for maintenance.
Respiratory Agents- Approval may be given for up to 12 months.
Skeletal Muscle Relaxants- Approval may be given for up to 6 months initially and up to 12 months for renewal requests for chronic conditions with muscle spasticity. For acute conditions approval may be granted for up to a 10-day course of medication consistent with current maximum limits when criteria are met.
Skin and Mucous Membrane Agents- Approval may be given for up to 12 months. For Elidel and Protopic, approval may be given for up to 3 months.
Specialized Nutritionals- Approval may be given for up to 12 months.
Sustained-Release Oral Opioid Agonists- Approval may be given for up to 12 months.
Synagis®- Approval may be given for up to 5 months or through the end of RSV season (March 31), whichever comes first.
Triptans- Approval may be given for up to 6 months initially and up to 12 months for renewal requests**.**
Xenical®- Approval may be given for up to 3 months with initial request, and up to 6 months for each subsequent request for a total approval period not to exceed 2 years for the recipient.
Xolair®- Approval may be given for up to 6 months for initial request and up to 12 months for renewal requests.

Section Two: Patient Information

- Record the patient's name as it appears on their Medicaid card, and their Medicaid number.

- Record patient's date of birth.
- Fill in the patient's phone number with area code.
- Indicate whether the patient is a nursing home resident.

Section Three: Prescriber Information

- Record the prescribing practitioner's name and license number, along with phone number and fax number with area codes. Mailing address is optional.
- The prescriber should sign and date in this section on the prescribing practitioner signature line. By signing in the space indicated, the practitioner verifies that the request complies with Medicaid's guidelines and that he/she will be supervising the patient during treatment with the requested product. The practitioner further certifies that documentation is available in the patient record to justify the requested treatment.

Section Four: Dispensing Pharmacy Information

- Information in this area may be completed by the pharmacy.
- Enter the pharmacy name and provider number.
- Enter phone number and fax number with area code.
- Record the NDC number.

Section Five: Drug/Clinical Information

- **This information is required for all requests.**
- Record the name of the drug and the strength requested.
- Enter the J code if the drug requested is to be administered using office medications.
- Enter the quantity of the drug requested per month.
- Circle the number of refills requested.
- Record diagnosis(es) that justifies the drug requested. Diagnosis(es) **or** ICD-9 code(s) may be used. Use of ICD-9 codes provides specificity and legibility and will usually expedite review.
- Indicate whether this is a first request or renewal request.
- Explain the reason this drug is required, and attach any additional medical justification necessary. Medical justification is documentation to support the physician's choice of the requested course of treatment. Documentation from the patient record (history and physical, tests, past or current medication/treatments, patient's response to treatment, etc) illustrates and supports the physician's request for the drug specified. For example, if a recommended therapy trial is contraindicated by the patient's condition or a history of allergy to a first-line drug, and the physician wants to order a non-preferred drug, documentation from the patient record would support that decision.

Section Six: Drug Specific Information

Alzheimer's Agents*/ Antidepressant Agents*/ Antidiabetic Agents/ Antihistamine Agents/ Antihypertensives Agents/ Anti-infective Agents/ Antilipemic Agents*/ Anxiolytic, Sedative and Hypnotic Agents*/ Cardiac Agents*/ Cerebral Stimulants/ Agents used for ADD/ADHD*/ EENT Antiallergic Agents*/ EENT Vasoconstrictor Agents*/ Estrogen Agents/ H2 Antagonist Agents/ Intranasal Corticosteroids Agents/ Narcotic Analgesic Agents*/ NSAID Agents/ Platelet-Aggregation Inhibitor Agents*/ PPI Agents*/ Respiratory Agents/ Skeletal Muscle Relaxants*/ Skin and Mucous Membrane Agents/ Triptans

- Prior authorization requires that two (2) prescribed generic, OTC or brand name drugs have been utilized unsuccessfully relative to efficacy and/or safety within six (6) months prior to requesting the PA. Those classes denoted with an asterisk (*) require two (2) prescribed and preferred agents, generic, OTC or brand, be utilized unsuccessfully within the past six (6) months. The PA request must indicate that two (2) generic, OTC or other brand drugs have been utilized for a period of at least thirty (30) days each (14 days for EENT Antiallergic Agents or Triptans; 3 days for EENT Vasoconstrictor Agents), **unless** there is an adverse/allergic response or contraindication. If the prescribing practitioner feels there is a medical reason for which the patient should not be on a preferred generic, OTC or brand drug, medical justification may be submitted in lieu of previous drug therapy. One prior therapy is acceptable in those instances when a class has only one preferred agent, either brand, generic or OTC, for a specific indication.
- Check the applicable drug classification requested. For H2 antagonists and PPIs, note whether this request is for **acute** or **maintenance therapy.**
- List previous prescribed and/or preferred drugs that were used unsuccessfully (generic, OTC, or brand name drugs) and the reason that each drug was discontinued. **If there were no failed trials with other drugs, additional medical justification must be provided to justify the request.**
- For those classes in which "stable therapy" is allowed if the patient has been stable (same drug and strength) on the requested drug for the timeframe specified in the specific drug class, medications provided through a government or state sponsored drug assistance program for uninsured patients may be counted toward the stable therapy requirement. Providers will be required to document this information on the PA request form and note the program through which the medication was dispensed. Medications paid for through insurance, private pay or Medicaid are counted toward the requirement.
- If the drug requested is a second generation **Antihistamine**, the patient must have an appropriate diagnosis supported by documentation in the patient record. The patient must also have failed 30-day trials with at least two prescribed agents in this class, either generic, OTC or brand within the past 6 months, or have documentation of an allergy or contraindication to all preferred agents in this class. Approval may be given for children age 18 years and under who have documented stable therapy on the requested medication for 60 consecutive days or greater.
- If the drug requested is an **Antidepressant,** the patient must have an appropriate diagnosis supported by documentation in the patient record.

The patient must also have failed 30-day trials with at least two prescribed and preferred agents in this class, either generic, OTC or brand within the past 6 months, or have documentation of an allergy or contraindication to all preferred agents in this class. Approval may be given to those who have documented stable therapy on the requested medication for 60 consecutive days or greater.

- If the drug requested is a **COX II,** please submit medical justification, which should include the relevant diagnosis, any additional diagnoses, and any history preventing the use of other NSAIDs. Approval may be given for children age 18 years and under who have documented stable therapy on the requested medication for 60 consecutive days or greater.
- If the drug is an **H2 Antagonist,** approval may be given without failed drug trials **if** a relevant diagnosis and documentation of testing with date and results are provided.
- If the drug requested is a **PPI** and there were no failed trials with preferred agents in this class, medical justification must be submitted documenting testing with date and results. Additional medical justification is diagnosis driven and outlined as follows:

GERD

For **mild to moderate GERD (Grade I, II, or III)**, medical justification documentation **must** indicate failure of preferred agents in this class prescribed for at least 8 weeks with persistence of symptoms. Testing is not required for acute therapy with moderate to severe symptoms, defined as ≥ 2 episodes/week of nocturnal heartburn, and ≥ 3 episodes/week of daytime heartburn or indigestion, with no resolution or worsening of symptoms. Approval may be given for up to 4 weeks of **acute** therapy. If moderate to severe symptoms persist and there is documentation in the medical record, an additional 8 weeks of treatment may be approved without testing. If symptoms persist, documentation of appropriate testing (barium contrast or double contrast radiography, or endoscopy) with results is required for approval of additional **maintenance** therapy.

For **severe GERD (Grade IV or V)**, diagnosis must be confirmed by testing (barium contrast or double contrast radiography, or endoscopy) within the past 12 months. For acute therapy, the patient may be approved for up to 8 weeks of therapy. If severe GERD symptoms continue or do not resolve, approval for **maintenance** therapy may be given for an additional 12 weeks of treatment.

Positive H. pylori

If the patient has tested positive for H. pylori (breath test, blood test or tissue biopsy if endoscopic exam done) and met prior usage requirements, approval may be given for up to 2 weeks of combination therapy. Requests for Prevpac® should meet Prevpac® criteria, not PPI criteria.

Gastric ulcer, duodenal ulcer, or esophagitis

The patient must have an appropriate diagnosis confirmed by testing (barium contrast or double contrast radiography, or endoscopy) within the past 12 months and meet prior usage requirements. If these requirements are met, up to 8 weeks of **acute** therapy may be approved. If on completion of 8 weeks of acute treatment for esophagitis (erosive or non-erosive) symptoms persist, approval may be given for up to 6 months of maintenance treatment. After 12 months, approval will require documentation of persistent symptoms and the results of retesting.

Hypersecretory conditions

If the patient is diagnosed with Barrett's Esophagitis, Zollinger-Ellison, or other hypersecretory disorders, which have been confirmed by testing (barium contrast or double contrast radiography, or endoscopy), then approval of up to 12 months of **acute** treatment may be issued, with continued **maintenance** therapy approved in 12 month increments. Renewal requests do not require retesting but do need documentation of persistence of symptoms.

For **Prevacid NapraPac**™ the patient must have a diagnosis of gastric ulcer, diagnosed within the past 12 months, **and** require the use of an NSAID for treatment of the signs and symptoms of rheumatoid arthritis, osteoarthritis, or ankylosing spondylitis. The patient must also have failed two 30-day treatment trials with at least two prescribed NSAIDs while on concomitant H2 or PPI therapy within the past 6 months, either generic, OTC or brand, or have a documented contraindication to all preferred agents in this class.

For **Prevpac**® the patient must have a diagnosis of duodenal ulcer, confirmed by testing within the past 12 months, and must also test positive for H pylori, confirmed by testing within the past 30 days. The patient must have failed two acute treatment trials of at least 14 days each with lack of healing on an acid suppressor and antibiotics, either generic, OTC or brand, within the past 6 months or have a documented contraindication to all preferred agents in these classes.

- If the drug requested is a **Narcotic Analgesic,** the patient must have an appropriate diagnosis supported by documentation in the patient record. Medical justification may be submitted in lieu of prior usage requirements. For Subutex® and/or Suboxone®, the patient must have the diagnosis of opioid type dependence and the physician must have received a waiver and special DEA number through the Center for Substance Abuse Treatment (CSAT) to practice medication-assisted opioid addiction therapy. For all other narcotic analgesics, medical justification must include documentation of therapeutic pain management failure with NSAIDs, APAP, or ASA and a complete pain evaluation in the medical record. Type of pain (acute versus chronic) and pain intensity (mild, moderate or severe) must be indicated in the Drug/Clinical Information section, under Medical Justification. Approval may be given for children age 18 years and under who have documented stable therapy on the requested medication for 60 consecutive days or greater.

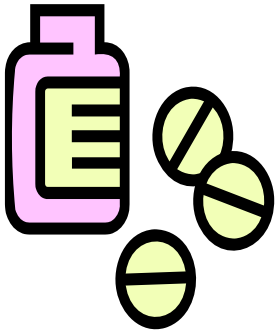
- If the drug requested is a **Platelet Aggregation Inhibitor,** the patient must have an appropriate diagnosis supported by documentation in the patient record. Medical justification may be submitted in lieu of prior usage requirements. Acceptable medical justification consists of specific clinical diagnoses for 1st line treatment by certain branded products in lieu of prior usage, contraindication or intolerance to the use of ASA, cilostazol, ticlopidine and dipyridamole. Clinical literature and guidelines support the use of Plavix or Aggrenox for specific 1st line indications; these indications include Acute Coronary Syndrome (Unstable Angina and Non-ST Elevation Myocardial Infarction, Non ST-Elevation ACS), Ischemic Stroke occurring while on ASA, Transient Ischemic Attack (TIA) occurring while on ASA, Percutaneous Coronary Interventions (balloon angioplasty, laser

angioplasty, intra-coronary stents, other catheter devices treating coronary atherosclerosis), and Myocardial Infarction or Ischemic Stroke occurring in patient with Peripheral Artery Disease (PAD/PVD). The date of the most recent event must be included in the Clinical Information section of the Prior Authorization Form. Approval may be given for children age 18 years and under who have documented stable therapy on the requested medication for 60 consecutive days or greater.

- If the drug is a **Skeletal Muscle Relaxant**, the patient must have an appropriate diagnosis supported by documentation in the patient record. If the patient has not failed a 30-day trial with at least two prescribed and preferred skeletal muscle relaxants, either generic, OTC or brand, within the past six months, approval may be given if the patient has been on consecutive 60-day or greater treatment with the skeletal muscle relaxant being requested for a **chronic** condition associated with muscle spasticity. The request may also be approved for an acute pain or musculoskeletal condition with documented allergy or contraindication to all preferred agents in this class. Approval may be given for children age 18 years and under who have documented stable therapy on the requested medication for 60 consecutive days or greater.
- If the drug is an **Anxiolytic, Sedative or Hypnotic,** the patient must have an appropriate diagnosis supported by documentation in the patient record. The patient must also have failed 30-day trials with at least two prescribed and preferred agents in this class, either generic, OTC or brand within the past 6 months, or have documentation of an allergy or contraindication to all preferred agents in this class. Approval may be given for children age 18 years and under who have documented stable therapy on the requested medication for 60 consecutive days or greater.
- If the drug is an **Antilipemic Agent,** the patient must have an appropriate diagnosis supported by documentation in the patient record. The patient must also have failed 30-day trials with at least two prescribed and preferred lipid lowering agents, either generic, OTC or brand, within the past 6 months, or have documentation of an allergy or contraindication to all preferred agents in this class. If prior usage requirements have not been met, approval may be obtained for adjunctive therapy to a current lipid lowering drug. Approval may be given for children age 18 years and under who have documented stable therapy on the requested medication for 60 consecutive days or greater.
- If the request is for a **Cerebral Stimulant** or an **Agent used to Treat ADD/ADHD**, the patient must have an appropriate diagnosis supported by documentation in the patient record. If the request is for a short- or intermediate-acting cerebral stimulant/agent used to treat ADD/ADHD, the patient must also have failed a 30-day trial with at least two prescribed and preferred short- or intermediate-acting cerebral stimulants/agents used for ADD/ADHD, either generic, OTC or brand, within the past 6 months. If the request is for a long-acting cerebral stimulant/agent used for ADD/ADHD, the patient must also have failed a 30-day trial with at least two prescribed and preferred long-acting cerebral stimulants/agents used for ADD/ADHD, either generic, OTC or brand within the past 6 months. For agents with an FDA-approved indication of narcolepsy or sleep apnea, the patient must have an appropriate diagnosis supported by documentation in the patient record of appropriate diagnostic testing. In lieu of prior usage

requirements, approval may be given if there is documentation in the patient's medical record of an allergy or contraindication to all preferred agents in this class, or valid medical justification is attached. Approval may be given to those who have documented stable therapy on the requested medication for 60 consecutive days or greater.

- If the drug is an **Antihypertensive,** the patient must have an appropriate diagnosis supported by documentation in the patient record. The patient must have failed 30-day treatment trials with at least two prescribed antihypertensive agents, generic, OTC or brand, or have a documented contraindication to all preferred agents in this class. To meet these prior usage requirements, drugs within this specific classification must be judged against others in the same class (AHFS specific). For example, to qualify for a non-preferred beta blocker, the patient must have met prior usage requirements of 30-day treatment trials with two other beta blockers, either generic, OTC or brand. Approval may be given for those who have documented stable therapy on the requested medication for 60 consecutive days or greater.
- If the drug is an **Estrogen,** the patient must have an appropriate diagnosis supported by documentation in the patient record. The patient must also have failed 30-day treatment trials with two other prescribed agents in this class within the past 6 months, either generic, OTC or brand, or have a documented allergy or contraindication to all preferred agents in this class. Approval may be given for children age 18 years and under who have documented stable therapy on the requested medication for 60 consecutive days or greater.



- If the drug is a **Triptan,** the patient must have an appropriate diagnosis supported by documentation in the patient record and the request must be for acute treatment, not prophylactic therapy. The patient must also have failed 2-week treatment trials with two other prescribed Triptans, either generic, OTC or brand, within the past 6 months or have a documented allergy or contraindication to all preferred agents in this class. Approval may be given for children age 18 years and under who have documented stable therapy on the requested medication for 60 consecutive days or greater.
- If the drug is a **Respiratory Agent,** the patient must have an appropriate diagnosis supported by documentation in the patient record. The patient must also have failed 30-day treatment trials with at least two other prescribed respiratory agents in this class, either generic, OTC or brand, within the past 6 months or have a documented allergy or contraindication to all preferred agents in this class. Requests for Pulmicort Respules™ or Singulair® will not require failed therapy for children under age five with a diagnosis of asthma. Approval may be given for children age 18 years and under who have documented stable therapy on the requested medication for 60 consecutive days or greater.
- If the drug is a **Cardiac Agent,** the patient must have an appropriate diagnosis supported by documentation in the patient record. The patient must also have failed a 30-day treatment trial with at least two prescribed and preferred cardiac agents in this class, either generic, OTC or brand, within the past 6 months or have a documented allergy or contraindication to all preferred agents in this class. To meet these prior usage requirements, drugs within this specific classification must be judged against others in the same class (AHFS specific). For example, to qualify for a non-preferred cardiotonic, the patient must have met prior usage requirements of 30-day treatment trials with two other preferred cardiotonic agents, either generic, OTC or brand. Approval may be given for those who have documented stable therapy on the requested medication for 60 consecutive days or greater.

- If the drug is an **EENT Antiallergic Agent,** the patient must have an appropriate diagnosis supported by documentation in the patient record. For ophthalmic products, the patient must also have failed 14-day treatment trials with at least two other prescribed and preferred ophthalmic agents in this class, either generic, OTC or brand, within the past 12 months or have a documented allergy or contraindication to all preferred agents in this class. For nasal products, in addition to documentation of an appropriate diagnosis, the patient must have failed 14-day treatment trials with at least two antiallergic agents, to include oral antihistamines, intranasal corticosteroids or intranasal cromolyn, either generic, OTC or brand within the past 12 months. Approval may be given for children age 18 years and under who have documented stable therapy on the requested medication for 60 consecutive days or greater.
- If the drug is an **EENT Vasoconstrictor Agent,** the patient must have an appropriate diagnosis supported by documentation in the patient record. The patient must also have failed 3-day treatment trials with at least two other prescribed and preferred agents in this class, either generic, OTC or brand, within the past 6 months. Approval may be given for children age 18 years and under who have documented stable therapy on the requested medication for 60 consecutive days or greater.
- If the drug is an **Intranasal Corticosteroid,** the patient must have an appropriate diagnosis supported by documentation in the patient record. The patient must also have failed 30-day treatment trials with at least two other prescribed intranasal corticosteroids in this class, either generic, OTC or brand, within the past 6 months or have a documented allergy or contraindication to all preferred agents in this class. Approval may be given for children age 18 years and under who have documented stable therapy on the requested medication for 60 consecutive days or greater.
- If the drug is an **Alzheimer's Agent,** the patient must have an appropriate diagnosis supported by documentation in the patient record for approval. The patient must also have failed a 30-day treatment trial with at least one prescribed and preferred Alzheimer's agent in this class, either generic, OTC or brand, within the past 6 months, or have a documented allergy or contraindication to all preferred agents in this class. Stable therapy for this class is defined as a 90-day or greater timeframe. Approval may be given for those who have documented stable therapy on the requested medication for 90 consecutive days or greater.

- If the drug is an **Antidiabetic Agent,** the patient must have an appropriate diagnosis supported by documentation in the patient record. The patient must also have failed 30-day treatment trials with at least two other prescribed diabetic agents in this class, either generic, OTC or brand, within the past 6 months, or have a documented allergy or contraindication to all preferred agents in this class. Approval may be given for those who have documented stable therapy on the requested medication for 60 consecutive days or greater.
- If the drug is a **Skin and Mucous Membrane Agent,** the patient must have an appropriate diagnosis supported by documentation in the patient record. The patient must also have failed 30-day treatment trials with at least two other prescribed skin and mucous membrane agents in this class, or one when appropriate based on PDL preferred agents, either generic, OTC or brand, within the past 6 months, have a documented allergy or contraindication to all

preferred agents in this class or have sufficient medical justification for approval in lieu of treatment trials for branded drugs where there is no preferred, generic or OTC alternative. To meet prior usage requirements, drugs within this specific classification must be judged against others in the same class (AHFS specific). Approval may be given for children age 18 years and under who have documented stable therapy on the requested medication for 60 consecutive days or greater.

- If the drug is an **Anti-infective,** the patient must have an appropriate diagnosis supported by documentation in the patient record. The patient must also have failed two treatment trials of no less than three-days each, with other preferred and prescribed anti-infectives, either generic, OTC or brand, within the past 30 days or have a documented allergy or contraindication to all preferred agents in this class. Patients on anti-infective therapy while institutionalized once discharged or transferred to another setting or patients having a 60 day consecutive stable therapy may continue on that therapy with supportive medical justification. Approval may also be given, with medical justification, if the medication requested is indicated for first line therapy when there are no other indicated preferred agents available or if indicated by susceptibility testing or evidence of resistance to all preferred agents. Medical justification may be provided in the appropriate area on the request form or included as an attachment.

Sustained Release Oral Opioid Agonist

- Approval may be given for the treatment of intractable, chronic pain with oral SR opioid agonists (OxyContin®, Kadian®, Oramorph SR®, MS Contin®, Avinza™). These medications are narcotic analgesics and Schedule II controlled substances. They are not intended for use with acute pain, as a PRN analgesic or for short-term pain management (≤ 10 days). The patient must have failed 30-day trials with alternative pain management therapies and non-opioid adjuvant drugs to replace or enhance opioid analgesia, unless the primary diagnosis is an approved cancer diagnosis. Submission of a plan of action addressing continual medical monitoring, titration and a written signed contract for therapy is required for patients with a history of substance abuse or addiction, unless the patient is a nursing home resident. For nursing home residents with a history of substance abuse or addiction, medical justification may be submitted in lieu of a plan of action, alternate pain management choices and adjuvant therapy. For patients ≥ 65 years of age, medical justification may be provided in lieu of non-opioid adjuvant drugs.
- Indicate how long patient will require treatment with Sustained Release Opioid Agonists (SROAs).
- You must indicate whether drug is intended for PRN use. **SROAs are not for short-term pain management (≤ 10 days) or for PRN use.**
- Indicate the type of pain and severity. **SROAs are not intended for use with acute pain.**
- Indicate prior and/or current analgesic drugs used and alternative management choices. **The patient must have had failed 30-day trials with alternative pain management therapies and non-opioid adjuvant drugs to replace or enhance analgesia, unless the patient has an approved cancer diagnosis.**

- Indicate whether the patient has a history of substance abuse or addiction. **If the answer is yes, a treatment plan (a plan of action addressing continual medical monitoring, titration, and a written signed contract for therapy) must be attached to the request, unless the patient is a nursing home resident.**

Xolair®

- Prior authorization for treatment with Xolair requires that the patient's course of treatment be recommended by a board certified pulmonologist or a board-certified allergist.
- The patient must be 12 years of age or older.
- The patient must be symptomatic despite receiving a combination of either inhaled corticosteroid and leukotriene inhibitor **or** an inhaled corticosteroid and a long acting beta agonist **or** the patient must have required 3 or more bursts of oral steroids within the past 12 months.
- The patient must have had a positive skin or blood test reaction to a perennial aeroallergen.
- Appropriate IgE to mass ratios must be followed, with the baseline IgE levels between 30 IU/ml and 700 IU/ml.
- The patient must weigh between 30kg and 150 kg.

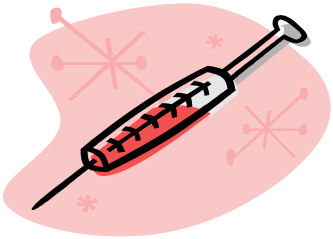
Biological Injectables

- Check the applicable drug.

A. Remicade® (Infliximab)

Rheumatoid Arthritis

For prior authorization the patient must have a diagnosis of rheumatoid arthritis [diagnosis of rheumatoid arthritis or other rheumatoid arthritis with visceral or systemic involvement, or polyarticular juvenile rheumatoid arthritis] that has been confirmed by a board-certified rheumatologist. The patient must also have a failed 30 day treatment trial with at least one conventional disease modifying antirheumatic drug (DMARD), at least one of which is methotrexate, unless there is a documented adverse response or contraindication to DMARD use. DMARDs include the following: hydroxychloroquine, sulfasalazine, methotrexate, leflunomide, d-penicillamine, azathioprine, oral gold, intramuscular gold. The patient will need to continue on methotrexate in conjunction with Remicade® therapy, unless there is a contraindication to its use. Any contraindications or intolerance to methotrexate use will need to be identified with appropriate supportive documentation included.



Crohn's Disease or Ulcerative Colitis

For prior authorization the patient must have a diagnosis of moderately to severely active Crohn's disease or ulcerative colitis [diagnosis of regional enteritis (Crohn's disease or granulomatous enteritis) of the small intestine, large intestine, small intestine with large intestine, and/or unspecified site, anal fistula and/or fistula of the intestine, excluding rectum and anus] that has been confirmed by a board-certified gastroenterologist. To be approved, the patient must have had an inadequate response (persistence of significant

and/or progressive weight loss, fevers, abdominal pain or tenderness, intermittent nausea or vomiting and/or significant anemia or increase or lack of reduction in the number of draining enterocutaneous fistulae in patients with fistulizing Crohn's disease) to one or more conventional therapies, which include aminosalicylates, corticosteroids, azathioprine/6-mercaptopurine, metronidazole, ciprofloxin, cyclosporin.

B. Enbrel® (Etanercept)

For prior authorization the patient must have a diagnosis of rheumatoid arthritis, polyarticular juvenile rheumatoid arthritis, psoriatic arthritis, chronic moderate to severe plaque psoriasis or active ankylosing spondylitis or plaque psoriasis. Submitted documentation must include evidence that the course of treatment with Enbrel® is recommended by a board-certified rheumatologist or dermatologist. The patient must also have failed a 30-day treatment trial with at least one conventional disease modifying antirheumatic drug (DMARD), unless there is a documented adverse response or contraindication to DMARD use.

C. Kineret® (Anakinra)

For prior authorization the patient must have a diagnosis of moderately to severely active rheumatoid arthritis. Submitted documentation must include a diagnosis of rheumatoid arthritis, confirmation of drug therapy by a board-certified rheumatologist, and a failed 30 day treatment trial with at least one conventional disease modifying antirheumatic drug (DMARD), unless there is a documented adverse response or contraindication to DMARD use.

D. Humira™ (Adalimumab)

For prior authorization the patient must have a diagnosis of moderately to severely active rheumatoid arthritis. Submitted documentation must include confirmation by a board-certified rheumatologist. The patient must also fail a 30 day treatment trial with at least one conventional disease modifying antirheumatic drug (DMARD), unless there is a documented adverse response or contraindication to DMARD use.

E. Orencia® (Abatacept)

For prior authorization the patient must have a diagnosis of moderately to severely active rheumatoid arthritis. Submitted documentation must include a diagnosis of rheumatoid arthritis, confirmation of drug therapy by a board-certified rheumatologist, and a failed 30 day treatment trial with at least one conventional disease modifying antirheumatic drug (DMARD), unless there is a documented adverse response or contraindication to DMARD use.

F. Raptiva™ (Efalizumab)

Raptiva is indicated for the treatment of chronic moderate to severe plaque psoriasis in adults 18 years or older who are candidates for systemic therapy or phototherapy.
The patient must have had a failed 6 month trial with topical treatment(s), either generic, OTC or brand, within the last year or documentation of allergy or

contraindication to all agents in this class. Patients may be taught to self inject, under the guidance and supervision of a physician. Granting of further approvals is dependent on patient compliance**.**

G. Amevive® (Alefacept)

Amevive is indicated for the treatment of chronic moderate to severe plaque psoriasis in adults 18 years or older who are candidates for systemic therapy or phototherapy. The patient must have had a failed 6 month trial with topical treatment(s), generic OTC or brand, within the last year or documentation of allergy or contraindication to all agents in this class.

Xenical®

- To receive prior authorization for Xenical®, the patient must be 18 years of age or older and have at least one of the following primary medical diagnoses: Diabetes Mellitus, Hypertension, or Hyperlipidemia.
- For initial requests the patient's height (in inches), weight (in pounds) and BMI are required.
- Renewal requests require the patient's previous and current weights (in pounds). **Continued weight loss must be documented for renewals.**
- There must be documentation in the patient record to support failure with prior physician supervised exercise/diet regimen(s) of at least 6 months duration. Documentation must also show that adjuvant therapy is planned.
- Dosage requested must not exceed 120 mg TID.

Phosphodiesterase Inhibitors

- Phosphodiesterase inhibitors require diagnosis of pulmonary arterial hypertension (defined by a mean pulmonary arterial pressure >25 mm Hg at rest or >30 mm Hg with exercise, by a pulmonary capillary wedge pressure < 15 mm Hg and by peripheral vascular resistance >3 mm Hg/L/min) with documentation of failure of or contraindication to at least three other available oral conventional therapies. Previous therapies may include oral anticoagulants, calcium channel blocking agents, digoxin, diuretics and/or oxygen supplementation. Documentation must be provided of consultation with a specialist experienced in the treatment of pulmonary hypertension patients.
- A sole diagnosis of erectile dysfunction or impotence will not be approved.

Synagis®

- Synagis® has been approved by Alabama Medicaid for the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) in pediatric patients at high risk for RSV disease. The patient must meet the gestational age, age at request requirements, and must be an outpatient with no in-patient stay for at least two weeks prior to the date of the medication request. Infants less than six (6) months old with gestational age of 33-35 weeks may qualify with 2 or more of the AAP risk factors (child care attendance,

school-age siblings, congenital abnormalities, severe neuromuscular disease, and exposure to environmental air pollutants).

- Environmental air pollutants do not include second-hand smoke. Environmental air pollutants would include instances where a child is **constantly** exposed to particulate air matter and should be described in detail in the Drug/Clinical information section of the PA form.
- Additional medical justification for high-risk toddlers less than twenty four (24) months of age may be given for hemodynamically significant CHD (Congenital Heart Disease) or CLD (Chronic Lung Disease) with documentation provided as defined. For CLD, documentation must support gestational age less than or equal to 35 weeks with parenchymal disease resulting from oxygen or ventilator support and ongoing medical intervention throughout the RSV season consisting of supplemental O2, bronchodilators, oral steroids, inhaled steroids, or diuretics. For hemodynamically significant CHD, the patient must be less than 24 months of age and documentation must show ongoing treatment consisting of home use of supplemental daily oxygen, diuretics, or other medications to control congestive heart failure, moderate to severe pulmonary artery hypertension or cyanotic congenital heart disease, and no surgical correction of cardiac defect.

- Patients who have received prior authorization should receive monthly doses (up to 5 doses) throughout the RSV season as defined by the Alabama Medicaid Agency. RSV prophylaxis approval will terminate after March 31.
- Current weight is required.
- In addition to the above, the patient must also be an outpatient with no inpatient stay within the past 2 weeks.
- Check appropriate category for age, condition, and risk factors.
- Approval authorizes only one (1) dose (based on patient weight) every thirty days up to a five (5) dose maximum or through March 31. The season will begin no earlier than October 1. **No request for more than five (5) doses will be approved. No dose may be given after March 31, and requests for more than one dose in a thirty-day period cannot be approved.**
- **Medical documentation acceptable for Synagis® prior authorization <u>must</u> include all medications, frequency of medication dosing, and diagnosis(es) with indications of severity of illness. A periodic review of medical records will be conducted by the Alabama Medicaid Agency or designees.**

<u>Specialized Nutritional</u>

- Patients who, because of illness or trauma, cannot be sustained through oral feedings and must rely on enteral nutrition therapy may qualify for coverage under Medicaid. Enteral nutrition may be administered by nasogastric, jejunostomy, or gastrostomy tubes.
- Specialized nutrition is covered for Medicaid eligible EPSDT recipients less than 21 years of age with nutritional disorders. They do not have to be

tube fed, but the specialized feeding must constitute more than 50% of their nutritional needs. A qualifying diagnosis is required.

- Recipients age 21 and over who must rely on enteral feedings as their only source of nutrition may qualify for Medicaid coverage if they have a qualifying diagnosis and meet disease specific criteria.
- Current height and weight are required.
- Select appropriate age category.
- Indicate how specialized nutritional is administered, along with the duration and number of refills.
- Prior authorization is for the nutritional product only and does not include any equipment or supplies necessary to administer the nutrients. Supplies and equipment used in conjunction with nutritional therapy may be covered in the Medical Supplies, Appliances and Durable Medical Equipment Program. For more information on supplies and equipment, see Chapter 14 of the Medicaid Provider Manual or contact Medicaid Provider/Recipient Services at 1-334-353-4753.

Section Seven: Exempt Medications

Currently only antipsychotics and HIV/AIDS drugs are exempt from the mandatory preferred drug list and new prior authorization requirements.